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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,071	10/23/2002	Michael E. O'Donnell	22221/1023	1435

7590 12/03/2004

Michael L Goldman
Nixon Peabody
Clinton Square
PO Box 31051
Rochester, NY 14603-1051

EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,071

Applicant(s)

O'DONNELL ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- | | |
|-------------|---|
| Group I | claims 1, 2-6 and 55-57 drawn to isolated DNA polC gene, <i>S.pyogenes</i> |
| Group II | claims 1, 7-11 and 55-57 drawn to isolated DNA dnaE gene, <i>S.pyogenes</i> |
| Group III | claims 1, 12-16 and 55-57 drawn to isolated DNA holA gene, <i>S.pyogenes</i> |
| Group IV | claims 1, 17-20 and 55-57 drawn to isolated DNA polC gene, <i>S.aureus</i> |
| Group V | claims 1, 21-25 and 55-57 drawn to isolated DNA holB gene, <i>S.pyogenes</i> |
| Group VI | claims 1, 26-29 and 55-57 drawn to isolated DNA holB gene, <i>S.aureus</i> |
| Group VII | claims 1, 30-34 and 55-57 drawn to isolated DNA dnaX gene, <i>S.pyogenes</i> |
| Group VIII | claims 1, 35-39 and 55-57 drawn to isolated DNA dnaN gene, <i>S.pyogenes</i> |
| Group IX | claims 1, 40-44 and 55-57 drawn to isolated DNA sib gene, <i>S.pyogenes</i> |
| Group X | claims 1, 45- 49 and 55-57 drawn to isolated DNA dnaG gene, <i>S.pyogenes</i> |
| Group XI | claims 1, 50- 54 and 55-57 drawn to isolated DNA dnaB gene, <i>S.pyogenes</i> |
| Group XII | claims 58 and 59-61 drawn to isolated protein alpha large <i>S.pyogenes</i> |
| Group XIII | claims 58 and 62-64 drawn to isolated protein alpha small <i>S.pyogenes</i> |
| Group XIV | claims 58 and 65-69 drawn to isolated protein delta <i>S.pyogenes</i> |
| Group XV | claims 58 and 70-74 drawn to isolated protein delta prime <i>S.pyogenes</i> |
| Group XVI | claims 58 and 75-77 drawn to isolated protein tau protein <i>S.pyogenes</i> |
| Group XVII | claims 58 and 78-80 drawn to isolated protein beta <i>S.pyogenes</i> |
| Group XVIII | claims 58 and 81-83 drawn to isolated SSB protein <i>S.pyogenes</i> |

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Group XIX claims 58 and 84-86 drawn to isolated DnaG protein *S.pyogenes*

Group XX claims 58 and 87-89 drawn to isolated DnaB protein *S.pyogenes*

Group XXI claims 90 and 91 drawn to a method of identifying a compound which inhibit the activity of a polymerase product of polC or dnaE

Further restriction to one product is required (see paragraph # 3).

2. The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Groups I-XI is considered to be isolated DNA which are made up of nucleic acids. The special technical feature of Groups XII-XX is considered to be protein, which is made up of amino acids. Thus Group I-XI inventions share no common structure, property and function with Group XII-XX invention since proteins contain amino acids.

Since the special technical feature of the Group I-XI inventions is not present in the Group XII-XX claims, unity of invention is lacking.

Pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that where multiple products, processes and methods are claimed, the main invention shall consists of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly the main invention (Group 1) comprises DNA, which is the first product.

Further pursuant to 37 C.F.R. 1.475 (d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. Therefore, the groups of inventions

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above do not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

3. The inventions listed as Groups I and XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I-XI is drawn to nucleic acids and Group XII-XX is drawn to polypeptides, that comprise amino acids. Thus these two groups lack the same or corresponding special technical features. Group XXI invention represents various methods using products that lack unity of invention as described above in Groups I-XI and XII-XX.

Lack of unity among genes:

4. The genes listed above in groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Genes as recited in Group I–XI, *polc* gene, a *dnaE* gene, a *holA* gene, a *holB* gene, a *dnaX* gene, a *dnaN* gene, a *ssb* gene, a *dnaG* gene, or a *dnaB* gene contain nucleic acid sequences SEQ.ID.NO: 11, 13, 17, 19, 21, 23, 25, 27, 29, 31 and 33 from *S.pyogenes* or *S.aureus*. These sequences are drawn to nucleic acid sequence that lack the same or corresponding special technical features because each sequence contains a specific nucleic acid sequence and do not share any common structure, property and function. They are structurally different to each other since each sequence has been identified with a specific sequence identification number that contains specific nucleic acids. In the instant case the different inventions represent structurally different nucleic acids. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have

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different effects. Thus, each sequence is unique and lacks the same or corresponding special technical features.

Lack of unity among proteins:

5. Groups XII –XX are drawn to different amino acid sequences as represented by SEQ.ID.NO: 12, 14, 18, 20, 22, 24, 26, 28, 30, 32 and 34 and lack the same or corresponding special technical features because each sequence contains a specific amino acid sequences. They are structurally different to each other since each sequence has been identified with a specific sequence identification number that contains specific amino acids. In the instant case the different inventions represent structurally different amino acids. Therefore, where structural identity is required, such as for expression, the different sequences have different effects. Thus, each sequence is unique and lacks the same or corresponding special technical features.

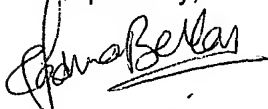
6. Restriction is required under 35 U.S.C. 121 and 372 to elect any one group from I-XXII and inform the examiner the specific gene or SEQ.ID.NO. If applicant elects group XXI invention, then applicant is advised to elect one gene or SEQ.ID.NO and inform the examiner clearly the same. Applicant is required, in reply to this action, to elect a group and SEQ.ID.NO to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

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8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Padma Baskar Ph.D.